

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

CLASSEN IMMUNOTHERAPIES,
INC.,

Plaintiff,
v.

KING PHARMACEUTICALS, INC.,
et al.,

Defendants.

CIVIL NO.: WDQ-04-3521

* * * * *

Memorandum Opinion

Classen Immunotherapies, Inc. ("Classen") has sued Elan Corporation, PLC, and Elan Pharmaceuticals, Inc. ("Elan") for patent infringement. Elan has counterclaimed alleging noninfringement, unenforceability of Classen's patents, defamation, false light invasion of privacy and unfair competition. Pending are Elan's motions for summary judgment, for clarification, to seal, and for discovery. Also pending is Classen's motion for partial summary judgment. For the following reasons, Elan's motion for summary judgment, for clarification, and to seal will be granted. Elan's motion for discovery and Classen's motion for partial summary judgment will be denied.

I. Background

Classen Immunotherapies, Inc. ("Classen") is a Maryland corporation that has developed and patented methods for

identifying and commercializing new uses of existing drugs. Complaint, p. 1. Classen is the holder of Patents 6,219,674 B1, "System for Creating and Managing Proprietary Product Data" (the "674 patent"), and 6,584,472 B2, "Method, System and Article for Creating and Managing Proprietary Product Data" (the "472 patent"). *Id.*

Elan is an Irish pharmaceutical company. Until 2003, Elan produced Skelaxin, a muscle relaxant.

In 2001, Elan learned of a study, conducted by a generic drug manufacturer, that indicated that Skelaxin's rate of absorption differed inside and outside the body. Elan conducted its own study in July 2001, and found that food had a significant impact on Skelaxin's bioavailability. Browning Decl., Ex. 1. Based on these findings, Elan submitted a Citizen Petition to the FDA requesting that the FDA require drug manufacturers seeking approval of generic forms of Skelaxin to submit fed and fasted studies in Abbreviated New Drug Applications ("ANDA"). Elan also submitted a labeling supplement to its own New Drug Application ("NDA")¹ for Skelaxin that included the results of the study. *Id.* at Ex. 3.

The FDA granted Elan's request for a requirement of fed and fasted studies for all generic Skelaxin ANDAs and approved Elan's

¹Submitted pursuant to § 505(b) of the Federal Food, Drug and Cosmetic Act ("FDCA").

amendments to the Skelaxin product label. Browning Decl., Ex. 2,3. Elan was also ultimately granted patent numbers 6,407,128 and 6,683,102 on the relabeled Skelaxin. Goldman Decl, ¶ 4.

Classen alleges that Elan infringed the 472 and 674 patents when it: 1) studied the effect of food on the bioavailability of Skelaxin; 2) used the study data to identify a new use of the drug; and 3) commercialized the new use. Plaintiff's First Supplemental Response to Defendant Elan Pharmaceuticals Interrogatory No. 3. Elan has moved for summary judgment on Classen's claims.

Elan has counterclaimed, arguing that Elan did not infringe Classen's patents, the patents are unenforceable, and that Classen defamed Elan, invaded its privacy and damaged its business by issuing a false press statement and by claiming that Elan and Classen had an ongoing business relationship. Classen has moved for summary judgment on Elan's defamation, invasion of privacy and damage to business claims.

II. Elan's Motion for Summary Judgment

Under Rule 56(c), summary judgment is appropriate when there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury

could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In considering a motion for summary judgment, "the judge's function is not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id.* at 249. Thus, "the judge must ask . . . whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented." *Id.* at 252.

The court must view the facts and reasonable inferences drawn therefrom "in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). However, the opposing party must produce evidence upon which a reasonable fact finder could rely. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). The mere existence of a "scintilla" of evidence is insufficient to preclude summary judgment. *Anderson*, 477 U.S. at 252.

Elan has moved for summary judgment arguing that even if its conduct fell within the scope of the 674 and 472 patents (which it does not concede), it is immune from patent enforcement under the "safe harbor" provision of the Patent Act, 35 U.S.C. § 271(e)(1), because the results of its research were submitted to the Food and Drug Administration ("FDA"). Classen argues in response that § 271(e)(1) is inapplicable to the patents and the conduct in question.

Under § 271, "whoever without authority makes, uses, offers to sell, or sells any patented invention...infringes the patent."

35 U.S.C. § 271(a). Section 271(e)(1), however, provides that:

[i]t shall not be an act of infringement to make, use, offer to sell or sell...a patented invention...solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs....

35 U.S.C. § 271(e)(1).

The Supreme Court has interpreted § 271(e)(1) broadly, holding that the provision "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Merck KgaA v. Integra Life Sciences I, Ltd.*, 125 S.Ct. 2372, 2380 (2005)(emphasis in the original). According to the Court, "there is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." *Id.*

Even assuming that Elan employed Classen's patented process when it studied Skelaxin's bioavailability problem and used the results to repatent the drug, the results of the 2001 study were submitted to the FDA in Elan's Citizen Petition and labeling supplement to its NDA. Therefore, Elan's use of the patented process was reasonably related to the submission of information under the FDCA and so is protected under § 271(e)(1).

Accordingly, Elan's motion for summary judgment will be granted.²

III. Classen's Motion for Partial Summary Judgment

In its December 12, 2005 order, the Court granted Elan's motion to amend its answer to add counterclaims for defamation, false light invasion of privacy and unfair competition. Classen has moved for partial summary judgment, arguing that Elan has failed to offer sufficient evidence in support of the new claims.

A. Defamation

Elan has alleged that Classen defamed Elan when it accused Elan of patent infringement in a November 29, 2004 press release; that the allegations are false; that Classen made the statement with malice or at least negligence; and that Elan's business reputation was harmed as a result. Elan has further alleged that Elan's business reputation was harmed when Classen claimed to have a business relationship with Elan in promotional materials sent to other pharmaceutical companies.

To recover for defamation under Maryland law, a plaintiff must establish that: 1) the defendant made a defamatory statement

²The Supreme Court in *Merck* specifically declined to rule on whether the use of "research tools" was protected under § 271(e)(1). *Merck*, 125 S.Ct. at n. 7. Although the Classen process could be considered a "research tool" the Court finds extension of the safe harbor to cover the use of these tools warranted by the language of *Merck* and a plain reading of the statute.

regarding the plaintiff to a third person; 2) the statement was false; 3) the defendant was legally at fault; and 4) the plaintiff was harmed as a result. *Holt v. Camus*, 128 F.Supp.2d 812 (D.Md. 1999). A defamatory statement is one that tends to expose a person to public scorn, hatred, contempt or ridicule, thereby discouraging others in the community from having a good opinion of, or from associating or dealing with, that person. *Batson v. Shiflett*, 325 Md. 684, 722-723 (Md. 1992).

Classen has moved for summary judgment arguing that Elan has failed to prove that the press release was false, that the statement was defamatory, that Classen was at fault and that Elan was harmed as a result.

As the Court has found that Elan did not infringe the Classen patent, Classen's accusation in the 2004 press release was false. Because Classen accused Elan of patent infringement, the accusation was a potentially defamatory statement. As Classen impugned Elan's business reputation, it has potentially defamed Elan *per se* and, therefore, harm is assumed. Whether Classen was legally at fault for making the statement (whether he made the statement with knowledge of its falsity or with reckless disregard of its falsity), remains a genuine issue in dispute. Accordingly, Classen's motion for summary judgment on Elan's defamation claim will be denied.

B. False Light Invasion of Privacy

To make a claim for false light invasion of privacy Elan must establish: (1) it was exposed to publicity that portrayed it in a false light; (2) a reasonable person would find the publicity highly offensive; and (3) Classen had knowledge of the falsity of the publicity or acted in reckless disregard of its truth or falsity. *Holt*, 128 F.Supp.2d 812.

In moving for summary judgment Classen again argues that the statements made in the press release were true. However, as noted above, the Court has found that Elan did not infringe the Classen patents and, therefore, the statements are false. As the release accuses Elan of patent infringement, a reasonable person might find the statements highly offensive. Additionally, as noted above, Classen's legal fault remains in dispute. Accordingly, Classen's motion for summary judgment on the false light invasion of privacy counterclaim will be denied.

C. Unfair Competition

Unfair competition is generally defined as "damaging or jeopardizing another's business by fraud, deceit, trickery or unfair methods." *Cavalier Mobile Homes, Inc. v. Liberty Homes, Inc.* 53 Md.App. 379 (Md. Ct. Spec. App. 1983); *Baltimore Bedding Co. v. Moses*, 182 Md. 229 (Md. 1943).

Classen argues for summary judgment of Elan's claim of

unfair competition on the grounds that its allegations of patent infringement are true. However, as the Court has found that Elan did not infringe the Classen patents, Classen's argument is without merit. Accordingly, Classen's motion for summary judgment of Elan's unfair competition claim will be denied.

D. Conclusion

For the reasons stated above, Classen's motion for partial summary judgment will be denied.

IV. Elan's Motions for Discovery

Elan's motion to add its counterclaims was granted on December 6, 2005. Discovery closed on December 16, 2005. Elan has now moved to reopen discovery for 45 days to answer Classen's motion for partial summary judgment pursuant to Rule 56(f), and in order to gather additional evidence for presentation at trial. Elan argues that it needs further discovery to substantiate its counterclaims and because Classen has persistently refused to comply with discovery requests.

As the Court has denied Classen's motion for partial summary judgment, Elan's motion for additional discovery to answer Classen's motion pursuant to Rule 56(f) will be denied as moot.

As Elan failed to move for a continuation of discovery or to compel discovery between the time its motion to amend its answer

was granted and the time discovery closed, the Court will not reopen the discovery process. Accordingly, Elan's motion for additional discovery to gather evidence to present at trial will be denied.

V. Elan's Motions to Seal

On May 11, 2005 the parties entered into a stipulated protective order regarding the confidentiality of discovery material. Under the protective order a party can designate material confidential if the person providing the material believes in good faith that it contains sensitive information, trade secrets or commercial information. Protective Order, ¶ 1(a). Motions filed with the Court that refer to or include information designated confidential are to be filed under seal. *Id* at ¶ 2. A designation of confidentiality may be challenged through a subsequent motion to the Court. *Id* at ¶ 5.

Elan has moved to seal: 1) its Opposition to Classen's Motion for Partial Summary Judgment; 2) its Reply in Support of its Motion for Summary Motion; 3) Classen's Motion for Partial Summary Judgment; and 4) Classen's Opposition to Elan's Motion for Summary Judgment. Elan argues for sealing the motions in question on the grounds that they contain reference to and in some cases include, the deposition testimony of Perry Goldman, Nancy Santilli and Steve Cartt; testimony which Elan classified

as confidential on November 16, 2005 and December 19, 2005. Elan has also moved to sanction Classen for its failure to abide by the terms of the protective order. Classen opposes the motions to seal arguing that Elan has failed to show that sealing is necessary.

As Classen failed to oppose the designation of Goldman's, Santilli's and Cartt's testimony as confidential, it cannot now oppose Elan's motion to seal or refuse to abide by the terms of the protective order. Accordingly, Elan's motion to seal: 1) its Opposition to Classen's Motion for Partial Summary Judgment; 2) its Reply in Support of its Motion for Summary Motion; 3) Classen's Motion for Partial Summary Judgment; and 4) Classen's Opposition to Elan's Motion for Summary Judgment will be granted.

VI. Motion for Clarification

On December 6, 2005, the Court granted summary judgment to defendant King Pharmaceutical ("King"). On December 20, 2005, the Court granted judgment to King. Elan has moved for clarification of the Court's December 20, 2005, order and requests that the Court: 1) declare that it was not granting King final judgment under Federal Rule of Civil Procedure Rule 54(b); and 2) strike Classen's improper notice of appeal.

As claims against Elan and Classen remained before the Court at the time, the Court's December 20, 2005, order did not grant

judgment for King under Rule 54(b). As the Federal Circuit has already dismissed Classen's appeal, Elan's request to strike Classen's notice of appeal is moot.

VII. Conclusion

For the reasons stated above, Elan's motion for summary judgment will be granted; its motions for additional discovery will be denied; its motions to seal will be granted; and its motion for clarification will be granted. Classen's motion for partial summary judgment will be denied.

August 16, 2006
Date

/s/
William D. Quarles, Jr.
United States District Judge